IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

CHARLES D. HOWELL, an individual; WOODROW A. JONES, an individual; PATRICIA NICHOLS, an individual; and WILLIAM J. PEARCE, SR., an individual,	)	
Plaintiffs,	)	
VS.	)	**CIVIL ACTION NO. 08-684**
SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE, a Pennsylvania corporation; GLAXOSMITHKLINE plc, an English public limited company; GLAXO WELLCOME UK LTD., Uxbridge, Middlesex, UK; and GLAXOSMITHKLINE UK LIMITED BRENTFORD, Middlesex, UK,	)	
Defendants.	)	

COMPLAINT

Plaintiffs, CHARLES D. HOWELL an individual; WOODROW A. JONES, an individual; PATRICIA NICHOLS, an individual; WILLIAM J. PEARCE, SR., an individual; (hereinafter "Plaintiffs"), by and through their counsel of record, hereby allege in their complaint against the Defendants, SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE, a Pennsylvania corporation; GLAXOSMITHKLINE plc, an English public limited company; GLAXO WELLCOME UK LTD., Uxbridge, Middlesex, UK; and GLAXOSMITHKLINE UK LIMITED BRENTFORD, Middlesex, UK, as follows:

JURISDICTION

1. Jurisdiction is based on diversity of citizenship under 28 U.S.C. § 1332. The matter in controversy exceeds the sum of Seventy-Five Thousand ($75,000.00) Dollars, exclusive of interest and costs.

2. This court has supplemental jurisdiction under 28 U.S.C. § 1367 with respect to claims that form part of the same case or controversy.

PARTIES

3. Plaintiffs are, and at all times mentioned herein were, citizens of the State of Alabama, and nineteen (19) years of age or older.

4. SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, a Pennsylvania corporation, was, and still is, a corporation duly existing under and by virtue of the laws of the State of Pennsylvania with its principal place of business in Philadelphia, Pennsylvania.

5. At all times relevant, Defendant, SmithKline Beecham Corporation, d/b/a GlaxoSmithKline was, and still is, a pharmaceutical company involving in researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing and marketing of pharmaceuticals for distribution, sale, and use by the general public, including its antidiabetic agent rosiglitazone maleate under the trade names of Avandia Tablets, Avandamet Tablets, and Avandaryl Tablets.

6. GlaxoSmithKline plc, an English public limited company was, and still is, a public limited company existing under and by virtue of the laws of the country of England with its principal place of business in London, England.

7. At all times relevant, Defendant GlaxoSmithKline plc was, and still is, a pharmaceutical company involved in researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing and marketing of pharmaceuticals for distribution, sale, and use by the general public, including its antidiabetic agent rosiglitazone maleate under the trade names of Avandia Tablets, Avandamet Tablets, and Avandaryl Tablets.

8. Glaxo Wellcome UK Ltd., Uxbridge, Middlesex, UK was, and still is, a public limited company existing under and by virtue of the laws of the country of England with its principal place of business in Uxbridge, Middlesex, England.

9. At all times relevant, Defendant Glaxo Wellcome UK Ltd. was, and still is, a pharmaceutical company involved in researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing and marketing of pharmaceuticals for distribution, sale, and use by the general public, including its antidiabetic agent rosiglitazone maleate under the trade names of Avandia Tablets, Avandamet Tablets, and Avandaryl Tablets.

10. GlaxoSmithKline UK Ltd., Brentford, Middlesex, UK, was, and still is, a public limited company existing under and by virtue of the laws of the country of England with its principal place of business in Brentford, Middlesex, England.

11. At all times relevant, Defendant GlaxoSmithKline UK Ltd. was, and still is, a pharmaceutical company involved in researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing and marketing of pharmaceuticals for distribution, sale, and use by the general public,

including its antidiabetic agent rosiglitazone maleate under the trade names of Avandia Tablets, Avandamet Tablets, and Avandaryl Tablets.

12. SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, a Pennsylvania corporation; GlaxoSmithKline plc, an English public limited company; Glaxo Wellcome UK Ltd., Uxbridge, Middlesex, UK; and GlaxoSmithKline UK Ltd., Brentford, Middlesex, UK hereinafter shall be collectively referred to as "GSK Defendants."

FACTUAL ALLEGATIONS

13. Rosiglitazone maleate ("rosiglitazone") is researched, manufactured, sold, merchandised, advertised, promoted, labeled, analyzed, tested, distributed and marketed by the GSK Defendants under the trade names of Avandia Tablets, Avandamet Tablets, and Avandaryl Tablets (hereinafter collectively referred to as "Avandia"), and is a member of the class of drugs known as Thiazolidinediones ("TZDs"). Avandia was first approved for use in the United States by the Food and Drug Administration ("FDA") in 1999 for the use in treatment of type 2 diabetes mellitus, also known as non-insulin-dependent diabetes mellitus.

14. Defendant distributed, prescribed and/or sold Avandia to consumers such as the Plaintiffs.

15. Most people with diabetes have risk factors such as high blood pressure and cholesterol that provide a pre-existing susceptibility for heart disease and stroke. More than 65 percent of deaths in patients with diabetes are from cardiovascular causes. The effect of any antidiabetic therapy is particularly important because the reason for the antidiabetic therapy is to reduce the complications of diabetes, the most serious of which is heart disease.

16. During the past decade, drugs have been introduced for the treatment of type 2 diabetes that, used in monotherapy or in combination therapy, are supposed to better control the disease in patients and reduce health complications associated with diabetes, such as heart attacks, strokes, and other cardiovascular complications.

17. Before or after the time when Avandia was prescribed and used by the Plaintiffs, the GSK Defendants knew, or should have known, that Avandia was associated with a significant increased risk of heart failure, myocardial ischemia and ischemic events such as cardiovascular mortality, myocardial infarction, and stroke.

18. The risk of heart failure, also referred to as congestive heart failure, in patients taking Avandia led to labeling revisions as marketing experience and the results of further clinical trials were reviewed by the Food and Drug Administration.

19. Before and at or about the time of Plaintiffs' ingestion of Avandia, the GSK Defendants had the knowledge, the means, and the duty to provide the medical community and the consuming public with more accurate descriptive information and more adequate warnings regarding the association between Avandia and heart failure, and the association between Avandia and myocardial ischemia and ischemic events such as cardiovascular mortality, myocardial infarction, and stroke, through all means necessary, including, but not limited to, labeling, continuing education, symposia, posters, sales calls to doctors, advertisements, and promotional materials.

20. At all times relevant, the GSK Defendants failed and refused to warn prescribing medical providers, and the consuming public, of the risks associated with Avandia that were known, or should have been known, as alleged herein.

21. At all times relevant, the GSK Defendants engaged in extensive mass

media direct-to-consumer promotion, education, and advertising of Avandia for the purpose of increasing sales and stimulating consumer requests for Avandia prescriptions, independent of the advice of medical professionals.

22. At all times relevant, Defendants, and each of them, and their aggregates, corporates, associates, and partners, and each of them, were the agent, servant, employee, assignee, permissive user, successor in interest, or joint venturer of each other, and were acting within the time, purpose, or scope of such agency or employment or permission; and all acts or omissions alleged herein of each such Defendant were authorized, adopted, approved, or ratified by each of the other Defendants.

COUNT I – NEGLIGENCE

23. Plaintiffs restate each and every prior and subsequent allegation of this Complaint and incorporate each by reference as though set forth in full herein.

24. At all times relevant, the GSK Defendants were under a duty to exercise reasonable care in the researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing and marketing of Avandia for distribution, sale, and use by the general public, to ensure that Avandia's use did not result in avoidable injuries.

25. Plaintiffs' injuries as described herein were caused by the negligence and misrepresentations of the GSK Defendants through its agents, servants and/or employees acting within the course and scope of their employment including among other things:

(a) Carelessly and negligently researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing and marketing Avandia;

(b) Failing to fully disclose the results of the testing and other information in its possession regarding the association between Avandia and heart failure, and the association between Avandia and myocardial ischemia and ischemic events such as cardiovascular mortality, myocardial infarction, and stroke;

(c) Negligently and carelessly failing to adequately warn the medical community and the general public, including the Plaintiffs and their treating and prescribing medical providers(s), of the dangers of using Avandia;

(d) Negligently and carelessly describing and promoting Avandia as safe and effective;

(e) Negligently and carelessly failing to act as a reasonably prudent drug manufacturer;

(f) Negligently and carelessly over-promoting and promoting Avandia in a zealous and unreasonable way, without regard to its potential dangers.

26. As a direct and proximate consequence of the negligence and breach of Defendants, the Plaintiffs sustained serious injuries. Defendants owed a duty to the Plaintiffs to use reasonable care.

COUNT II – NEGLIGENT FAILURE TO WARN

27. Plaintiffs incorporate by reference each and every prior and subsequent allegation of this complaint as if fully restated here.

28. Avandia was not accompanied by appropriate warnings of the increased risk of adverse side effects caused by the ingestion of Avandia.

29. Defendants negligently failed to warn consumers who took Avandia that it was dangerous.

30. Defendants' negligence was the proximate cause of the harm suffered by the Plaintiffs.

31. As a direct and proximate cause of Defendants' negligence:

(a) Plaintiffs suffered personal injuries;

(b) Plaintiffs suffered past and future economic loss; and

(c) Plaintiffs expended, and will in the future be required to expend, fair and reasonable expenses for necessary health care, attention and services and incur incidental and related expenses.

(d) Plaintiffs suffered and will continue to suffer emotional distress and mental anguish.

(e) Plaintiffs suffered and will continue to suffer from physical pain.

(f) Plaintiffs suffered past and future lost wages.

COUNT III – MISREPRESENTATION AND SUPPRESSION

32. Plaintiffs incorporate by reference each and every prior and subsequent allegation of this complaint as if fully restated here.

33. Defendants misrepresented to the Plaintiffs and to the health care industry the safety and effectiveness of Avandia and/or fraudulently, intentionally and/or negligently concealed material information, including adverse information regarding the safety and effectiveness of Avandia.

34. Defendants made misrepresentations and actively concealed adverse information at a time when the Defendants knew, or should have known, that Avandia had defects, dangers, and characteristics that were other than what the Defendant had represented to the Plaintiffs and the health care industry generally. Specifically,

Defendants misrepresented to and/or actively concealed from the Plaintiffs, the health care industry and consuming public that:

(a) Avandia had statistically significant increases in cardiovascular side effects which could result in serious injury or death;

(b) There had been insufficient and/or company-spun studies regarding the safety and efficacy of Avandia before and after its product launch;

(c) Avandia was not fully and adequately tested for the cardiovascular side effects at issue herein;

(d) Other testing and studies showed the risk of or actual serious adverse risks;

(e) There was a greatly increased risk of such cardiovascular events and death.

35. The misrepresentations of and/or active concealment alleged were perpetuated directly and/or indirectly by Defendants.

36. Defendants knew or should have known that these representations were false and made the representations with the intent or purpose that the Plaintiffs would rely on them, leading to the use of Avandia.

37. At the time of Defendants' fraudulent misrepresentations, Plaintiffs were unaware of the falsity of the statements being made and believed them to be true. Plaintiffs had no knowledge of the information concealed and/or suppressed by Defendants.

38. Plaintiffs justifiably relied on and/or were induced by the

misrepresentations and/or active concealment and relied on the absence of safety information which the Defendants did suppress, conceal or failed to disclose to Plaintiffs' detriment.

39. Defendants had a post-sale duty to warn Plaintiffs and the public about the potential risks and complications associated with Avandia in a timely manner.

40. The misrepresentations and active fraudulent concealment by the Defendants constitutes a continuing tort against the Plaintiffs, who ingested Avandia.

41. Defendants made the misrepresentations and actively concealed information about the defects and dangers of Avandia with the intention and specific desire that Plaintiffs' health care professionals and the consuming public would rely on such or the absence of information in selecting Avandia as treatment.

42. As a direct and proximate result of the fraudulent acts and omissions, suppression and misrepresentation of Defendants, Plaintiffs suffered significant and ongoing injury and damages.

COUNT IV – BREACH OF WARRANTY

43. Plaintiffs incorporate by reference each and every prior and subsequent allegation of this complaint as if fully restated here.

44. When Defendants placed Avandia into the stream of commerce, Defendants knew of the use for which it was intended and expressly and impliedly warranted to the Plaintiffs that use of Avandia was a safe and acceptable means of treatment.

45. Plaintiffs reasonably relied upon the expertise, skill, judgment and

knowledge of the Defendant and upon the express and/or implied warranty that Avandia was of merchantable quality and fit for use as intended.

46. Avandia was not of merchantable quality and was not safe or fit for its intended use because it was and continues to be unreasonably dangerous and unfit for the ordinary purposes for which it is used in that it caused injury to the Plaintiffs. Defendants breached the warranty because Avandia was unduly dangerous in expected use and did cause undue injury to the Plaintiffs.

47. Defendants breached the implied warranty of merchantability because Avandia cannot pass without objection in the trade, is unsafe, not merchantable, and unfit for its ordinary use when sold, and is not adequately packaged and labeled.

48. As a direct and proximate result of Defendants' breach of the warranty of merchantability, Plaintiffs sustained serious and permanent injuries.

COUNT V – BREACH OF EXPRESS WARRANTY

49. Plaintiffs incorporate by reference each and every prior and subsequent allegation of this complaint as if fully restated here.

50. Defendants expressly warranted to the market, including the Plaintiffs, by and through statements made by Defendants or its authorized agents or sales representatives, orally and in publications, package inserts, and other written materials to the health care community, that Avandia was safe, effective, fit and proper for its intended use.

51. In using Avandia, Plaintiffs relied on the skill, judgment, representations,

and foregoing express warranties of Defendants. Those warranties and representations proved to be false because the product was not safe and was unfit for the use for which it was intended.

52. As a direct and proximate result of Defendants' breach of warranties, the Plaintiffs were injured and suffered special and compensatory damages to be proven at trial.

COUNT VI – FRAUD

53. Plaintiffs incorporate by reference each and every prior and subsequent allegation of this complaint as if fully restated here.

54. Defendants committed actual fraud by making material representations as stated herein which were false, knowing that such material representations were false and/or with reckless disregard for the truth or falsity of such material representations, with the intent that the Plaintiffs relied on such material representations; Plaintiffs acted in actual and justifiable reliance on such material representations and were injured as a result.

55. In addition, and in the alternative if necessary, Defendants knowingly omitted material information, which omission constitutes a positive misrepresentation of material fact, with the intent that the Plaintiffs relied on Defendants' misrepresentations; Plaintiffs acted in actual and justifiable reliance on Defendants' representations and were injured as a result.

56. Defendants committed constructive fraud by breaching one or more legal

or equitable duties owed to the Plaintiffs relating to Avandia at issue in this lawsuit, said breach or breaches constituting fraud because of their propensity to deceive others or constitute an injury to public interests or public policy.

COUNT VII – FRAUDULENT INDUCEMENT AND SUPPRESSION

57. Plaintiffs incorporate by reference each and every prior and subsequent allegation of this complaint as if fully restated here.

58. Defendants misrepresented to the Plaintiffs and the health care industry the safety and effectiveness of Avandia and/or fraudulently, intentionally and/or negligently concealed material information, including adverse information regarding the safety and effectiveness of Avandia.

59. Defendants made misrepresentations and actively concealed adverse information at a time when the Defendants knew, or should have known, that Avandia had defects, dangers, and characteristics that were other than what the Defendants had represented to the Plaintiffs and the health care industry generally. Specifically, Defendants misrepresented to and/or actively concealed from the Plaintiffs, the health care industry and consuming public that:

(a) Avandia had statistically significant increases in cardiovascular side effects which could result in serious injury or death;

(b) There had been insufficient and/or company-spun studies regarding the safety and efficacy of Avandia before and after its' product launch;

(c) Avandia was not fully and adequately tested for the cardiovascular side effects at issue herein;

(d) Other testing and studies showed the risk of or actual serious

adverse risks;

(e) There was a greatly increased risk of such cardiovascular events and death.

60. The misrepresentations of and/or active concealment alleged were perpetuated directly and/or indirectly by Defendants.

61. Defendants knew or should have known that these representations were false and made the representations with the intent or purpose that the Plaintiffs would rely on them, leading to the use of Avandia.

62. At the time of Defendants' fraudulent suppression, Plaintiffs were unaware of the falsity of the statements being made and believed them to be true. Plaintiffs had no knowledge of the information concealed and/or suppressed by Defendants.

63. Plaintiffs justifiably relied on and/or were induced by the misrepresentations and/or active concealment and relied on the absence of safety information which the Defendants did suppress, conceal or failed to disclose to the Plaintiffs' detriment.

64. Defendants had a post-sale duty to warn Plaintiffs and the public about the potential risks and complications associated with Vioxx in a timely manner.

65. The misrepresentations and active fraudulent concealment by the Defendants constitute a continuing tort against the Plaintiffs, who ingested Avandia.

66. Defendants made the misrepresentations and actively concealed

information about the defects and dangers of Avandia with the intention and specific desire that Plaintiffs' health care professionals and the consuming public would rely on such or the absence of information in selecting Avandia as treatment.

67. As a direct and proximate result of the fraudulent acts and omissions, suppression and misrepresentation of Defendants, Plaintiffs suffered significant and ongoing injury and damages.

COUNT VIII – ALABAMA EXTENDED MANUFACTURER'S LIABILITY DOCTRINE (AEMLD)

68. Plaintiffs incorporate by reference each and every prior and subsequent allegation of this complaint as if fully restated here.

69. Defendants are liable to the Plaintiffs pursuant to the AEMLD. Defendants are in the business of manufacturing, distributing, and marketing Avandia. Defendants manufactured, distributed, and marketed Avandia which was in a defective condition, and unreasonably dangerous when applied to its intended use in the usual, foreseeable, and customary manner. Plaintiffs, while consuming Avandia in the usual and customary manner, as such was intended to be used, were injured and damaged as a proximate result of Defendants' placing the product on the market. Avandia was unreasonably dangerous at the time such was placed on the market by Defendants. Avandia, at the time of Plaintiffs' injuries and damages, was in substantially the same condition as when marketed by Defendants.

70. Defendants negligently or wantonly failed to give reasonable and adequate warning of dangers of Avandia known to Defendant, or which in the exercise of reasonable care should have been known to the Defendants, and which Plaintiffs could not obviously discover.

COUNT VIX – WANTONNESS

71. Plaintiffs incorporate by reference each and every prior and subsequent allegation of this complaint as if fully restated herein.

72. At all times relevant, the GSK Defendants were under a duty to exercise reasonable care in the researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing and marketing of Avandia for distribution, sale, and use by the general public, to ensure that Avandia's use did not result in avoidable injuries.

73. Plaintiffs' injuries as described herein were caused by the wantonness of the GSK Defendants through its agents, servants and/or employees acting within the course and scope of their employment including among other things:

(a) Carelessly and wantonly researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing, and marketing Avandia;

(b) Failing to fully disclose the results of the testing and other information in its possession regarding the association between Avandia and heart failure, and the association between Avandia and myocardial ischemia and ischemic events such as cardiovascular mortality, myocardial infarction, and stroke;

(c) Wantonly and carelessly failing to adequately warn the medical community and the general public, including the Plaintiffs and their treating and prescribing medical provider(s), of the dangers of using Avandia;

(d) Wantonly and carelessly describing and promoting Avandia as safe and effective;

(e) Wantonly and carelessly failing to act as a reasonably prudent drug manufacturer;

(f) Wantonly and carelessly over-promoting and promoting Avandia in a zealous and unreasonable way, without regard to its potential dangers.

74. As a direct and proximate consequence of the wantonness and breach of Defendants, the Plaintiffs sustained serious injuries. Defendants owed a duty to the Plaintiffs to use reasonable care.

DEMAND FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendants for damages, as well as all costs of this action, to the full extent of the law, including:

(a) Damages to compensate Plaintiffs for serious injuries sustained as a result of the use of Avandia, past and future lost income, past and future medical expenses as proven at trial;

(b) Damages for the wanton, reckless, intentional and/or wrongful conduct of the Defendants and to punish and deter similar wrongful conduct;

(c) Physical pain and suffering of Plaintiffs;

(d) Mental anguish and/or emotional distress;

(e) Permanent injury;

(f) Punitive damages; and

(g) Such other applicable damages as the Court deems appropriate.

/s/ C. Carter Clay
C. Carter Clay (ASB-2907-Y85C)
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JURY DEMAND

Plaintiffs hereby demand a struck jury for the trial in this cause.

/s/ C. Carter Clay
Of Counsel

SERVE THE FOLLOWING DEFENDANT BY CERTIFIED MAIL:

SmithKline Beecham Corporation
C/O CSC Lawyers Incorporating Service, Inc.
150 S. Perry Street
Montgomery, AL 36104